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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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HAMILTON, BROOK, SMITH & REYNOLDS, P.C.
530 VIRGINIA ROAD
P.O. BOX 9133
CONCORD, MA 01742-9133

EXAMINER	
GAMBEL, PHILLIP	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 10/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/927,703	LE ET AL.	
	Examiner	Art Unit	
	Phillip Gambel	1644	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-13 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-13 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . SEE OFFICE ACTION
4) ☒ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. The instant application is compliance with the Sequence Rules.

2. Claims 1-12 are pending.

3. Applicant's provision of faxed copies of the Information Disclosure Statements previously filed in the instant application is acknowledged.

However, neither all of the priority applications nor copies of the cited references were available to the examiner at this time. Therefore, the examiner has not signed all of the Information Disclosure Statements at this time. The examiner will provide the Information Disclosure statements in the next Office Action after efforts to obtain all of the references cited by applicant. Therefore, no Information Disclosure Statement is provided with this Office Action. The examiner apologizes for any inconvenience in this matter.

4. The filing date of the instant claims is deemed to be the filing date of the priority application USSN 08/570,674, filed 12/11/95, as the previous priority applications do not support the claimed limitations of the instant application, encompassing methods of treating "psoriasis".

If applicant disagrees, applicant should present a detailed analysis as to why the claimed subject matter has clear support in the earlier priority applications.

Applicant is reminded that such priority for the instant limitations requires written description and enablement under 35 U.S.C. § 112, first paragraph.

5. If applicant desires priority under 35 U.S.C. 120 based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No._____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

Also see United States Patent and Trademark Office OG Notices: 1268 OG 89 (18 March 2003).

6. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. Applicant should restrict the title to the claimed invention.

7. The Abstract of the Disclosure is objected to because it does not adequately describe the claimed invention. Correction is required. See MPEP 608.01(b).

8. The application is required to be reviewed and all spelling, TRADEMARKS, and like errors corrected

Trademarks should be capitalized or accompanied by the ™ or ® symbol wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate corrections are required.

9. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1, 3-5, 11-13: cA2 Antibody.

It is apparent that the cA2 antibodies are required to practice the claimed invention. As a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the appropriate cell line / hybridoma which produces this antibody. See 37 CFR 1.801-1.809.

Given the patented claims set forth in U.S. Patent No. 5,698,195 (Le et al.)(not provided), the requirement for the deposit of the biological materials cA2 antibodies under 35 USC § 112, first paragraph, enablement, has been satisfied.

Amendment of the specification to recite the date of deposit and the complete name and address of the depository is required. As an additional means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

It is noted that the sequence of an entire immunoglobulin satisfies the biological deposit of said immunoglobulin. Note that satisfaction for the biological deposit of the specific cA2 antibody requires the disclosure and recitation of its entire amino acid sequence and not based upon partial sequences.

11. Claims 1-13 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 1, 3-5, and 11-13 are indefinite in the recitation of "cA2" antibody because its characteristics are not known. The use of "cA2" antibody as the sole means of identifying the claimed antibody renders the claims indefinite because this designation is merely a laboratory designation which does not clearly define the claimed product, since different laboratories may use the same laboratory designation to define completely distinct cell lines.

Amending the claims to recite the appropriate ATCC Accession Numbers or the appropriate SEQ ID NOS. of the entire cA2 antibody would obviate this rejection.

Given the number of patents from the priority documents, applicant is invited to make a positive statement that the claimed cA2 antibody is the same cA2 antibody deposited by the appropriate ATCC Accession Numbers or set forth in the appropriate SEQ ID NOS. of the entire cA2 antibody would obviate this rejection.

If the intent of the recitation of cA2 is not a specific antibody but reflects a TNF specificity, then applicant is required to amend the claims to recite an ATCC Accession Number or the appropriate SEQ ID NOS. that define the cA2 to obviate this rejection.

B) Claims 1-13 are rejected because "TNF" and "hTNF" should be spelled out at least upon first time usage in the claims for clarity. Also, applicant should indicate tumor necrosis factor α" as the specificity of the claimed / disclosed antibodies.

C) Applicant should specifically point out the support for any amendments made to the disclosure. See MPEP 714.02 and 2163.06

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless --

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 1-2, 5-6, 11-12 are rejected under 35 U.S.C. § 102(e) as being anticipated by Adair et al. (U.S. Patent No. 5,994,510) (see entire document).

Adair et al. teach methods of inhibiting patients suffering disorders associated with undesirably high levels of TNF, including psoriasis (e.g. see columns 1-12, including column 11, line 52) with TNFα-specific antibodies, including recombinant chimeric and humanized antibodies(e.g., columns 5-12), including the use of IgG1 (e.g. column 9, paragraph 3) (see Detailed Description of the Invention) (see entire document).

The reference does not disclose that the "anti-TNF antibody competitively inhibits binding of TNF to monoclonal antibody cA2" or "anti-TNF antibody binds to at least one epitope included in amino acids between 87-108 or both 59-80 or 87-108 of SEQ ID NO: 1 of hTNF" of the claimed antibody specificity in the claimed methods to treat psoriasis.

Given the properties of the prior art TNFα-specific antibodies which include antibodies that neutralize TNF, including reducing or inhibiting a biological activity of human TNFα as measured by an in vitro or in vivo bioassay (e.g. see Summary of the Invention in column 5) as well as the referenced methods of inhibiting patients suffering disorders associated with undesirably high levels of TNF, including psoriasis (e.g. see columns 1-12, including column 11, line 52) with TNFα-specific antibodies;
the claimed functional limitations of "anti-TNF antibody competitively inhibits binding of TNF to monoclonal antibody cA2" or "anti-TNF antibody binds to at least one epitope included in amino acids between 87-108 or both 59-80 or 87-108 of SEQ ID NO: 1 of hTNF" would be inherent properties of the referenced methods to treat psoriasis with TNFα-specific antibodies.

Applicant is invited to distinguish the prior art TNFα-specific antibodies and the presently claimed TNFα-specific antibodies in methods of treating psoriasis. The Office is not equipped to make such comparisons.

15. Claims 1-13 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Adair et al. (U.S. Patent No. 5,994,510) in view of Le et al. (WO 92/16553).

Adair et al. teach methods of inhibiting patients suffering disorders associated with undesirably high levels of TNF, including psoriasis (e.g. see columns 1-12, including column 11, line 52) with TNFα-specific antibodies, including recombinant chimeric and humanized antibodies (see Detailed Description of the Invention) (see entire document).

Adair et al. differs from the claimed methods by not disclosing "anti-TNF antibody competitively inhibits binding of TNF to monoclonal antibody cA2" or "anti-TNF antibody binds to at least one epitope included in amino acids between 87-108 or both 59-80 or 87-108 of SEQ ID NO: 1 of hTNF" as the anti-TNFα antibody specificities employed in the claimed methods.

Le et al. (WO 92/16553) teach methods of treating autoimmune disorders with anti-TNFα antibody, including the cA2 anti-TNFα antibody specificity and including its epitopic specificity (e.g. pages 9-10, overlapping paragraph; page 13, paragraph 1; page 15, page 20; page 22) (see entire document, including Summary of the Invention, Detailed Description of the Preferred Embodiments and Examples).

Given the inhibitory properties of the cA2 TNFα-specific antibodies taught by Le et al., one of ordinary skill in the art at the time the invention was made would have been motivated to substitute the cA2 anti-TNFα antibody specificity into the methods of treating psoriasis with TNFα-specific antibodies taught by Adair et al. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

The references differ from the claimed methods by not disclosing the well known use of human antibodies in human therapy.

Given the well known use of therapeutic antibodies that have decreased immunogenicity to overcome neutralizing effects of the immune response in human patients, it had been well accepted practice by the ordinary skill in the art at the time the invention was made to employ therapeutic antibodies will decreased immunogenicity, such as chimeric antibodies, humanized antibodies, as taught above as well as human antibodies. One of ordinary skill in the art human antibodies, one of ordinary skill in the art at the time the invention was made would have been motivated to modify the anti-TNFα antibodies or the cA2-specific anti-TNFα antibodies by making them human to decrease immunogenicity in the methods of treating psoriasis with TNFα-specific antibodies taught by Adair et al. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

16. No claim allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 872-9306.

Phillip Gambel, PhD.
Primary Examiner
Technology Center 1600
September 29, 2003